

**REMARKS**

**Status of Claims**

Claims 1-6, 8-10, 13, 15-20, 22-24, 26-30 and 48-51 are pending in the application. Claims 1-6, 8-10, 13, 15-17, 19-20, 22-24, 26-30 and 48-51 are currently rejected. Claim 18 is allowed. Claim 13 is being cancelled in this response. Claims 4, 7, 11-12, 14, 21, 25, 31-47 were cancelled in previous amendments. Claims 1, 5, 6, 10, 15, 20, 22, 26, 48, and 50-51 have been amended. Claims 52-56 are new.

In light of the amendments and remarks herein, reconsideration of claims 1-3, 5, 6, 8-10, 15-20, 22-24, 26-30 and 48-56 is respectfully requested.

**Allowable Subject Matter**

Applicants note with appreciation the Examiner's indication that claim 18 is allowed.

**Amendments to the Claims**

While Applicants believe that the previously presented claims are patentable over all of the art cited in the Office Action, as well as all other references submitted by Applicants, the claims have nonetheless been amended as follows in order to expedite the allowance of the claims. The amendments are, therefore, made without prejudice or disclaimer, and Applicants reserve the right to pursue the original scope of the claims as provided prior to the cancellation or amendment of the claims, such as through continuation practice.

Claim 1 is amended to claim a method in which the power density is in the range of approximately  $0.35 \text{ W/cm}^2 - 10 \text{ W/cm}^2$ . Support for the amendment is found throughout the specification, including the original claims as filed. (See, e.g., ¶¶ 108 and 166.)

Claims 5 and 6 are amended to address the Examiner's concerns on pages 3 of the office action with regard to antecedent basis.

Claim 15 is amended to correct a grammatical error.

Claim 20 is amended to clarify that the wavelength or wavelengths used can be a single wavelength, multiple wavelengths, a range of wavelengths or ranges of wavelengths, and to clarify the meaning of the claim.

Claim 22 is amended to conform to the amendments of claim 20.

Claim 26 is amended to claim a method in which the power density in the range of approximately  $0.25 \text{ W/cm}^2 - 10 \text{ W/cm}^2$ . Support for the amendment is found throughout the specification, including the original claims as filed. (See, e.g., ¶¶ 108 and 166.)

Claim 48 is amended to eliminate the power density element. Support for the amendment is found throughout the specification, including the original claims as filed. (See, e.g., ¶¶ 108 and 166.)

Claims 50 and 51 are amended to conform to the amendments of claim 20.

Newly added claim 52 claims irradiating substantially an entire volume of blood in one treatment session. Support for the amendment is found throughout the specification, including the original claims as filed. (See, e.g., ¶¶ 148 and 166.)

Newly added claims 53-56 claim a method of biostimulation via an oral cavity. Support for the amendment is found throughout the specification, including the original claims as filed. (See, e.g., ¶¶ 108 through 166.)

**Claim Rejections - 35 U.S.C. § 112**

The Examiner rejected claims 5 and 6, because the term “said treatment sessions” lacked sufficient antecedent basis. Applicants have amended claims 5 and 6 to address the Examiner’s concerns.

**Claim Rejections - 35 U.S.C. § 102**

Claims 1-3, 5, 6, 8, 10, 13, 15-17, 20, 22, 26-29 and 48-51 were rejected under 35 U.S.C. §102(b) as anticipated, or in the alternative, under 35 U.S.C. 103(a) as obvious, over U.S. Patent

6,159, 236 to Biel. (herein "Biel"). These claims are patentable, however, because Biel fails to disclose all of the elements recited in the claims.

For example, Biel does not disclose eliminating pathogens located in the oral cavity or in tissue associated with the oral cavity using a light acceptor at the power density claimed and disclosed by applicants. Independent claim 1 (and the associated dependent claims) recites, among other things, "irradiating an area of tissue in the oral cavity with radiation from the phototherapy applicator, *the radiation having a power density in the range of approximately  $0.35 \text{ W/cm}^2 - 10 \text{ W/cm}^2$ .*" Biel, on the other hand, discloses a procedure that employs only low power. For example, Biel discloses a procedure that has "a light dosage rate ranging from about  $0 \text{ mW/cm}^2$  to about  $150 \text{ mW/cm}^2$ ." (See Biel at Col. 3, lines 5-11.) In contrast, the Applicants disclose and claim methods and devices capable of biostimulation at significantly higher power density, energy flux and total power.

Similarly, Biel does not disclose or suggest a method of treating blood via an oral cavity by irradiating an endogenous light acceptor as claimed in independent claim 20. Biel does not disclose any type of blood treatment, and, in fact, the Biel reference does not contain the word "blood."<sup>1</sup>

In rejecting claim 20 and dependent claim 27 in light of Biel, the Examiner noted at page 4 that the power and fluences of Biel allow treatment time will in excess of the time required for blood to circulate through a body. This is not sufficient to practice the claimed invention. Even assuming that the power and fluence disclosed by Biel may allow for Applicants claimed blood treatments, Biel still does not actually disclose those treatments. Biel does not describe how such treatments may be successfully performed, and there is nothing in Biel that suggests the devices and parameters disclosed in Biel would inherently practice the claimed invention. For example, Biel only generally discloses a range of wavelengths that may be used in photodynamic therapy, but nothing in Biel suggests that all (or any) of those wavelengths would successfully treat blood, if applied using the power and fluence parameters of Biel. In short, Biel is not an

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<sup>1</sup> The closest Biel comes to disclosing a treatment of blood is the mention of a prior art reference that concerns the removal of plaque from blood vessels, which does not concern the claimed invention. (See Biel Col. 1, line 45.)

enabling disclosure that would teach one skilled in the art to practice the claimed methods, and, thus, Biel does not anticipate or render obvious claims 20 and the claims dependent from claim 20.

With respect to the Examiner's comments regarding the definition of photodynamic therapy (PDT) on page 2, which formed part of the basis for the Examiner's rejections, the Applicants note that the definition of PDT presented by Applicants is a commonly accepted definition of the term by persons skilled in the art. However, the Applicants acknowledge that the definition of the term is not used uniformly, and that others skilled in the art do define PDT in a manner consistent with the Examiner's use of the term. While the Applicant's traverse the Examiner's rejections with respect to Biel and reserve the right to address the issue later in prosecution if necessary, Applicants also note that the present amendments to the claims render the issue moot at this point in time.

Claims 2-3, 5, 6, 8, 10, 15-17, 22, 26-29 and 48-51 are patentable for at least the reasons that Claims 1 and 20, from which each respectively depends, are patentable. Thus, claims 1-3, 5, 6, 8, 10, 15-17, 20, 22, 26-29 and 48-51 are in order for allowance.

**Claim Rejections - 35 U.S.C. § 103**

Claims 9 and 30 are rejected under 35 U.S.C. §103(a) as being unpatentable over Biel in further view of U.S. Patent 6,887,260 to McDaniel (herein "McDaniel"). Claim 19 was rejected under 35 U.S.C. §103(a) as being unpatentable over Biel in further view of U.S. Patent 6,135,774 to Hack (herein "Hack") and claims 23 and 24 were rejected under 35 U.S.C. §103(a) as being unpatentable over Biel in further view of U.S. Patent 6,026,828 to Altshuler (herein "Altshuler"). The Applicants disagree with the Examiner's application of Biel, McDaniel, Hack and Altshuler to these dependent claims. However, these claims are not obvious in light of the cited art, at a minimum, because none of the references discloses all of the elements of the independent claims from which each of the claims depend as discussed above. Therefore, Applicants submit that claims 9, 19, 23, 24 and 30 are patentable over the cited art.

### CONCLUSION

In summary, the above-identified patent application has been amended and reconsideration is respectfully requested for all the reasons set forth above. In the event that the amendments and remarks are not deemed to overcome the grounds for rejection, the Examiner is kindly requested to telephone the undersigned representative to discuss any remaining issues.

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